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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,179	02/13/2004	Kenji Hanabusa	248687US0	4459

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,179	HANABUSA ET AL.	
	Examiner	Art Unit	
	Andrew D Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/19/04, 7/12/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim 1-8 are pending in the instant application. Claims 1-8 are rejected.

Priority

Receipt is acknowledged of a certified copy of the PCT/JP03/05453 application referred to in the oath or declaration or in an application data sheet. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c).

Information Disclosure Statement

References AG-AV (PTO-1449, April 29,2004) and AP (PTO-1449, July 12, 2004) have been considered by the Examiner insofar as disclosed in the provided English abstracts and the statement of relevance within the instant specification.

Abstract

The abstract of the disclosure is objected to because it is more than one paragraph in length and more than 150 words in length. Correction is required. See MPEP § 608.01(b).

Examiner Notes

Herein, citations to relevant passages of U.S. Patents are as (Column #: line #), i.e.- (c3:1+). For foreign patents and non-patent literature it is as (Page #), i.e.- (p1), and when applicable (Page #: line or paragraph #), i.e.- (p1:4 or p1:p4).

Specification

The use of the trademark AMIHOPE LL (p10) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

Claims 1 is objected to because of the following informalities:

Claim 1 recites, "...formula (1). ... 2 to 4.)" The claim does not end in a period as is required, see MPEP 608.01 (m).

Claim 1 is two sentences, and is improper. Currently, the claim recites, "A basic amino acid ... (1). (In the formula ... 2 to 4.)", see MPEP 608.01 (m).

Claim 1 recites, "... (In the formula ... 2 to 4.)". While it is clear that Applicant is reciting the limitations for each functional group within the parentheses, parentheses are generally used to represent deleted text or reference numbers in a claim.

Claim 1 recites, "In the formula..." While it is clear that Applicant is claiming the variables present on formula (1), the claim would more clearly recite, "wherein..."

Claims 2-5 recite, "... the above formula..." Applicant is requested to remove "above", as in the printed patent formula (1) may not be print 'above'.

Claim 8 recites, "A perfumery/cosmetic ..." While it is clear that Applicant is claiming either embodiment, the claim would more clearly recite "A perfumery or cosmetic ..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 each recite, "one member of the basic amino acid derivative", however "member" is not defined in the claims or specification in such a manner as one of ordinary skill in the art would be reasonably apprised of the scope of the claimed invention. While it appears that Applicant intended to recite that the formulations comprise at least one derivative, the scope derived from the claim language is broader than the claim from which it depends. The scope of claims 6-8 encompasses the compounds of claim 1 as well as fragments of compound, while claim 1 allows only for compounds, therefore the claims are indefinite.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(a) as being anticipated by (A) Suzuki, *et al.*[1]

The instant claims are drawn to oxalyl amides, an example of which is bis(N^{ϵ}-lauroyl-lysine) derivative. The compounds are also formulated as gels.

(A) teaches bis(N^{ϵ}-lauroyl-lysine) derivates which are ester derivatives (p4125: compounds 1 – 25). Particularly, compound 11, where the spacer, n, is zero.

(A) teaches that these compounds have gel properties (p4125: tables 1 and 2) and that organogelators are used in cosmetics applications (p2124).

The teaching of compounds 1-25 as organogelators fully anticipate instant claims 1-4 and 6-8.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(a) as being anticipated by (B) Suzuki, *et al.*[2]

The instant claims are described *supra*.

(B) teaches compounds 1 – 7, bis(N^{ϵ}-lauroyl-lysine) derivates (p6842, Figure 1), and that these compounds are organogelators (p6841).

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[1] PTO-1449, 7/12/04: M Suzuki, et al. Tetrahedron Letters (2003) 44, 6841-6843.

The teaching of compounds 1-7 as organogelators fully anticipate instant claims 1-4 and 6-8.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (A) as applied to claims 1-4 and 6-8 above, in view of Gachard, *et al.*[3]

(A) teaches the compounds 1-25 as organogelators. (A) does not teach salts of these compounds. (A) teaches that the esters of N^{ϵ}-lauroyl-lysine are synthesized from the free acid form (*citing Hanabusa, et al. Chem. Lett. 2000, 1070-1071*).

Gachard teaches lysine-based polyamides with various viscosities (p1382) and teaches that, "...the carboxylic acid side groups should make the polymers water-soluble, and could also be used for covalently binding a drug for biomedical uses." (p1375) and similarly that, "[t]heir solubilization in water is expected to be possible after deprotection of whole or part of the benzyl ester group [of a lysine amide]" (p1388).

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[2] PTO-1449, 7/12/04: M Suzuki, et al. Org. Biomol. Chem. (2003) 1, 4124-4131.
[3] I Gachard, et al. Macromol Chem. Phys. (1997) 198, 1375-1389.

Therefore, it would have been obvious to one of ordinary skill in the art to use the non-ester form of the N^{ε}-lauroyl-lysine to make organogelators which are water-soluble, with a reasonable expectation for success in making the free acid, in view of the beneficial teachings of Gachard. One would be motivated to make the free acid form, as Gachard teaches that the compounds would be useful for temporarily immobilizing a drug.

Further, with regards to the salt form, it would have been obvious to one skilled in the art at the time of invention to determine all operable and optimum components, such as salt forms, because the isolation of a free-acid water-soluble compound as a salt form is an art-recognized result-effective variable that is routinely determined and optimized in the chemical and composition arts.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gachard as applied to claims 1-8 above and JP 2000-256303[4] (′303), and in further

[4] PTO-1449, 4/29/04, reference AV.

view of Makrevic, *et al.*[5], Ajinomoto[6] (C), Ajinomoto[7] (D), Suzuki, *et al.*[8] (E), U.S. Patent 4,965,071 (´071) and Cosmetic and Toiletry Formulations, Volume 5 (2nd Edition)[9] (Cosmetic).

The instant claims are described *supra*.

Cosmetic teaches that Amihope LL, the trade-name for lauroyl lysine, was known in 1996, and manufactured by Ajinomoto; (C) teaches the structure and chemical name of Amihope LL is N^{ϵ}-lauroyl-lysine; and (D) teaches that Amihope LL is, "an ideal ingredient for cosmetic products" (p3).

´303 teaches that N^{ϵ}-lauroyl-lysine was used as a starting material for making gels (Abstract); ´071 teaches Amihope-LL as a component of a wrinkle masking gel (c9: Examples 1 and 2), and thus the examiner has concluded that a gel is a cosmetic.

(E) teaches the synthesis of various forms of N^{ϵ}-lauroyl-lysine and esters (p1) which are used as gellators.

Makarevic teaches oxalyl amide gelators formed from various amino acids (p3329). Makarevic does not teach N^{ϵ}-lauroyl-lysine as an amino acid.

Gachard further teaches one embodiment as N^{α},$N^{\alpha'}$-adipoyl bis(N^{ϵ}-benzyloxycarebonyl-lysine-benzyl ester). Gachard does not teach N^{ϵ}-lauroyl-lysine.

It would have been obvious to one of ordinary skill in the art to use either the free-acid form or ester form of N^{ϵ}-lauroyl-lysine to make gelators with a reasonable

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[5] PTO-1449, 7/12/04, J Makarevic, et al. Chem. Eur. J. (2001) 7, 3328-3341.
[6] Amihope Functional Powder http://www.ajinomoto.co.jp/e_aminoscience/cosmetics/functional.html. Accessed 10/21/04. 1 page.
[7] Ajinomoto http://www.chembuyersguide.com/partners/ajinomoto.html. Accessed 10/21/04. 4 pages.
[8] M Suzuki, et al. Chem. Comm. Supplementary data (2001) 1-4.
[9] Cosmetic and Toiletry Formulations, Volume 5 (2nd Edition) ©1996. Page 591.

expectation of success in making a gel because Makarevic teaches oxalyl amides as gelators, Gachard teaches an N^{ϵ}-modified lysine polyamides with various viscosities and '303 teaches that N^{ϵ}-lauroyl-lysine was used as a starting material for gels and as part of a gel. Because they are N^{ϵ}-modified-lysine compounds used in gels, one of ordinary skill in the art would have been motivated to use the N^{ϵ}-lauroyl-lysine in the oxalyl amide of Makarevic or Gachard to increase the lipophilicity, generated by the alkyl chain, in a gel formulation.

Further, with regards to the salt form, it would have been obvious to one skilled in the art at the time of invention to determine all operable and optimum components, such as salt forms of a free-acid, because the isolation of a free-acid water-soluble compound as a salt form is an art-recognized result-effective variable that is routinely determined and optimized in the chemical and composition arts.

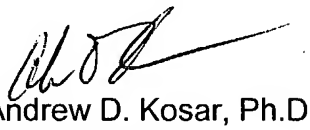
From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

NO CLAIMS ARE ALLOWED.

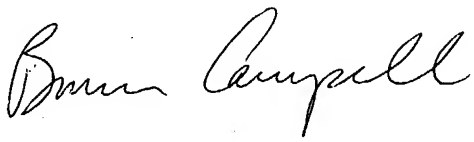
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew D. Kosar, Ph.D.
Patent Examiner
Art Unit 1654



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